April 1, 2021

VueSonic, LLC
% Marc Sanchez
Regulatory Attorney
Contract In-House Counsel and Consultants, LLC
1717 Pennsylvania Ave. NW, Suite #1025
Washington, D.C. 20006

Re: K210300
Trade/Device Names: VueSonic One Contact Lens Cleaning System,
VueSonic Advance 2 Contact Lens Cleaning System
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LYL, MRC
Dated: February 2, 2021
Received: February 3, 2021

Dear Marc Sanchez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Angelo Green, PhD
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210300

Device Name
VueSonic One Contact Lens Cleaning System
VueSonic Advance 2 Contact Lens Cleaning System

Indications for Use *(Describe)*

The VueSonic One Contact Lens Cleaning System is a cleaning system for Soft and Hybrid contact lenses by mimicking digital rubbing with 3-D sonic Vibration Technology.

The VueSonic Advance 2 Contact Lens Cleaning System is a cleaning system for Rigid contact lenses by mimicking digital rubbing with 3-D sonic Vibration Technology.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

The following information is provided as required by 21 CFR

807.92 for the VueSonic One Contact Lens Cleaning System and VueSonic Advance 2 Contact Lens Cleaning System 510(k) premarket notification.

Sponsor: VueSonic LLC
1234 Washington Ave, Suite 205
Miami Beach, FL 33139
Establishment Registration: to be determined
Ph: 855-770-0883

Manufacturer: VueSonic LLC
1234 Washington Ave, Suite 205
Miami Beach, FL 33139
Establishment Registration: to be determined
Ph: 855-770-0883

Contact: Marc C. Sanchez, Esq.
Contract In-House Counsel and Consultants, LLC
1717 Pennsylvania Ave. NW, Suite #1025
Washington, D.C. 20006
Ph: 202-765-4491
Email: msanchez@fdaatty.com

Date of 510(k) Summary Preparation: March 18, 2021

Proprietary Names: VueSonic One Contact Lens Cleaning System, VueSonic Advance 2 Contact Lens Cleaning System

Common Name: Accessories, Solution, Ultrasonic Cleaners For Lenses

Regulation Number: 21 CFR 886.5928/21 CFR 886.5918

Regulatory Class: Class II

Product Code: LYL/MRC

Predicate Device(s): New Comfort Contact Lens Accessory (K974724) and AUTOLENS® System (K021699)

Device Description: The VueSonic One Contact Lens Cleaning System and VueSonic Advance 2 Contact Lens Cleaning Systems are cleaning systems for contact lenses. Both devices consist of a device body, a contact lens holder, which houses the cleaning cushions and the damping heads. The contact lens holder, cleaning cushions and damping heads are made of soft medical silicone, which will not damage the lens. The systems are designed to mimic human hand rubbing. This is done by the 3D

multi-frequency.

The proposed device consists of two versions:

- For Rigid Lenses, VueSonic Advance 2 Contact Lens Cleaning System; and
- For Soft and Hybrid Lenses, VueSonic One Contact Lens Cleaning System.

VueSonic One:

The VueSonic One Contact Lens Cleaning System is a cleaning system for Soft and Hybrid contact lenses. It consists of a device body, a contact lens holder, which houses the cleaning cushions and the damping heads. The contact lens holder, cleaning cushions and damping heads are made of soft medical silicone, which will not damage the lens.

The system is de- signed to mimic human hand rubbing. This is done by the 3D multi-frequency modulated stereo power source and corresponding intelligent control circuit, which make a uniform three-dimensional relative movement between the damping heads and cleaning cushion.

The proposed device is compatible with Soft and Hybrid contact lens from all the brands with a diameter equal or less than 15mm. This limitation is due to the size of the device and in particular the damping head.

The proposed device is compatible with all "multi-purpose" cleaning solution such as Bausch & Lomb Multi-action Solution and Opti-Free. The only incompatible solution is Clear Care and Clear Care Plus because Clear Care requires its own standing case and contains 3% Hydrogen Peroxide, which may cause serious damage to eyes when used improperly.

VueSonic Advance 2

The VueSonic Advance 2 Contact Lens Cleaning System is a cleaning system for Rigid contact lenses. It consists of a device body, a contact lens holder, which houses the cleaning cushions and the damping heads. The contact lens holder, cleaning cushions and damping heads are made of soft medical silicone, which will not damage the lens. The system is designed to mimic human hand rubbing. This is done by the 3D multi-frequency modulated stereo power source and corresponding intelligent control circuit, which make a uniform three-dimensional relative movement between the damping heads and cleaning cushion.

The proposed device is compatible with Rigid contact lens from all the brands with a diameter equal or less than 15mm. This limitation is due to the size of the device and in particular the damping head.

The proposed device is compatible with all "multi-purpose" cleaning solution such as Bausch & Lomb Multi-action Solution and Opti-Free. The only incompatible solution is Clear Care and Clear Care Plus because Clear Care requires its own standing case and contains 3% Hydrogen Peroxide, which may cause serious damage to eyes when used improperly.

Indications for Use:

The VueSonic One Contact Lens Cleaning System is a cleaning system for Soft and Hybrid contact lenses by mimicking digital rubbing with 3-D sonic Vibration Technology.

The VueSonic Advance 2 Contact Lens Cleaning System is a cleaning system for Rigid contact lenses by mimicking digital rubbing with 3-D sonic Vibration Technology.

Summary of Non-Clinical Test Reports

The following tests were performed on the subject devices and the test results show that the devices are substantially equivalent to the predicate devices on the market.

Table 1
Summary of Non- Clinical Test Reports

Biocompatibility	Ocular Irritation	ISO 10993-10, 12
	In Vitro Cytotoxicity Test	ISO 10993-5
	Sensitization	ISO 10993-10
	Systemic Toxicity	ISO 10993-11, 12
Electrical Safety and Electromagnetic Compatibility	General Requirements electromagnetic compatibility	IEC 60601-1-2
	General Requirements electrical safety	IEC 60601-1
	General Requirements home healthcare environment	IEC 60601-1-11
Usability	Human Factor Engineering and Usability Engineering Evaluation Report	IEC62366-1:2015
Protein and Lipid Removal Test	Protein and Lipid Removal Test	Citation
Total Extractive Residues	Total Extractive Residues	FDA 21 CFR 177.2600

Software	Software Validation	FDA Guidance
Lens Compatibility Test	Lens Compatibility Test	ISO 18369-2:2017

Summary of Substantial Equivalence

The VueSonic One Contact Lens Cleaning System, VueSonic Advance 2 Contact Lens Cleaning System, and the predicates use a multipurpose contact lens solution and a physical mode of action to clean contact lenses. The proposed device uses a sophisticated multi-frequency modulated stereo power system, while K974724 uses ultrasonic waves and K021699 uses a tumbling motion. The different motions are all aimed at mimicking hand rubbing to physically clean contact lenses. There may be minor differences in labeling but this does not raise any new questions of safety or effectiveness.

Table 2 Technological Characteristics

Device Name/Model	Vue Sonic One Contact Lens Cleaning System, Vue Sonic Advance 2 Contact Lens Cleaning System	New Comfort Contact Lens Accessory	AUTOLENS® System
510(k) Number	K210300	K974724	K021699

Indications for Use	The VueSonic One Contact Lens Cleaning System is a cleaning system for Soft and Hybrid contact lenses by mimicking digital rubbing with 3-D sonic Vibration Technology. The VueSonic Advance 2 Contact Lens Cleaning System is a cleaning system for Rigid contact lenses by mimicking digital rubbing with 3-D sonic Vibration Technology.	The New Comfort Contact Lens Care Accessory is intended for use in conjunction with contact lens solutions as an accessory in the cleaning of contact lenses. The New Comfort Contact Lens Care Accessory is indicated as aid for cleaning as an accessory for soft hydrophilic lenses and gas permeable lenses when used with the appropriate Allergan® Soft Mate® solutions such as the	The AUTOLENS® Automatic Contact Lens Cleaning Accessory is indicated for the cleaning of soft (hydrophilic), rigid gas permeable (RGP) and hard (PMMA) contact 1enses when used with AUTOLENS® Multipurpose Solution. This automatic contact lens cleaning accessory cleans contact lenses without digital

		Consept® Cleaning and Disinfection System which is comprised of the Allergan® Soft Mate® Consept®-1 Cleaning and Disinfecting solution and Allergan® Soft Mate® Consept®-2 Neutralizing and Rinsing Solution or Spray. The New Comfort Contact Lens Care Accessory is indicated for use for gas permeable solutions such as Allergan® Gas Permeable Daily Cleaner and Allergan® ComfortCare GP Wetting and Soaking Solution. The New Comfort Contact Lens Care Accessory may be used for a receptacle for chemical disinfection.	rubbing. The AUTOLENS® Automatic Contact Lens Cleaning Accessory may be used as a receptacle for chemical disinfection with AUTOLENS® Multipurpose Solution. AUTOLENS® Multipurpose Solution is indicated for use in cleaning, rinsing, chemical (not heat) disinfecting and protein removal, storing soft (hydrophilic), rigid gas permeable fluoro-silicone acrylate and silicone acrylate) and PMMA contact lenses as recommended by your eye care practitioner.
Mode of Action	3D multi-frequency modulated stereo power source and corresponding intelligent control circuit, which make a uniform three dimensional relative movement between the damping heads and cleaning cushion	Bubbles created from piezo electric crystal (ultrasonic)	Tumble motion

Power Source	1.5~3V battery (one or two "AAA" batteries)	110/120v (standard power using four- foot UL cord)	1.5v (three "AA" batteries)
Materials	Medical grade silicone	ABS	Polypropylene resin plastic
Cleaning Time	2 minutes	Unknown	Unknown
Watts of Power per Milliliter of Fluid	0.37 to 0.72 watt/ ml	Unknown	Unknown

Conclusion:

Therefore, taking into consideration Table 1 for Substantial Equivalence, an analysis of safety, indications, intended uses, performance, and technological properties, the VueSonic Contact Lens Cleaning System raises no new issues of safety or effectiveness and has been found to be substantially equivalent to the predicate devices.